

Notice of Allowability

Application No.

10/691,094

Examiner

Janet L. Coppins

Applicant(s)

GRIFFIN ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' After-Final Amendment of 10/5/05.
2. ☒ The allowed claim(s) is/are 22-24 and 28-30.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
- ☐ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

DETAILED ACTION

Claims 22-24, and 28-30 are pending in the instant application.

Response to After-Final Amendment

1. Receipt is acknowledged of Applicants' After-Final Amendment, filed October 5, 2005, which has been entered. Accordingly, claims 26, 27, 32, and 33 have been cancelled, and claims 22 and 28 have been amended.

Claim Rejections - 35 USC § 112

2. The Examiner had previously rejected claims 22-24, 26-30, 32, and 33 under 35 USC 112, first paragraph, as not being enabled. In view of Applicants' amendments and cancellations to the claims, the rejections have been overcome and are withdrawn.

3. Claims 22-24 and 28-30 previously rejected under 35 U.S.C. 112, second paragraph as being indefinite. In view of the amendatory changes to the claims, the Examiner withdraws the rejections.

Allowable Subject Matter

4. Claims 22-24 and 28-30 are allowable, as renumbered claims 1-6. The following is an examiner's statement of reasons for allowance:

This invention relates to methods of using piperazine compounds and their compositions that are anti-proliferative agents. The claims in this case are 22-24 and 28-30, and the allowable methods are limited to treating AML, small cell lung cancer, prostate cancer, gastrointestinal cancer, breast cancer, brain cancer, and restnosis. The recited piperazine compounds and their compositions according to formula (Ia) have been previously prosecuted in the parent

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application, U.S. Appl. No. 10/327,385, which is now U.S. Pat. No. 6,686,362. However the methods of using said compounds for treating the above-mentioned diseases and disorders are neither anticipated nor fairly suggested by the prior art. After a thorough search, the closest of prior art, Chen et al, U.S. Pat. No. 6,130,239, was found to teach similar indoline compounds that are kinase inhibitors and anti-proliferative agents. However the '239 patent fails to disclose the same methods of using the recited compounds according to formula (Ia). Therefore, the prior art fails to teach, anticipate, or fairly suggest the instant claimed piperazine compounds, or their use as receptor tyrosine kinase inhibitors for treating the above-mentioned diseases. Applicants have demonstrated the ability of the instant claimed compounds to treat the specific cancers mentioned above in the biological assays of pages 25-28 of the specification as well as the numerous journal articles cited in the Informational Disclosure Statements of January 9, 2004, and May 6, 2005.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
November 23, 2005

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Kamal Saeed
Joseph K. McKane
SPE, Art Unit 1626